

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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| Applicant: | Li Wang | Examiner: | Alyssa M. Alter |
| Serial No.: | 10/684,759 | Group Art Unit: | 3762 |
| Filed: | October 14, 2003 | Docket: | P0011118.00 |
| | | Conf. No.: | 3360 |
| Title: | METHOD AND APPARATUS FOR MONITORING TISSUE FLUID CONTENT FOR USE IN AN IMPLANTABLE CARDIAC DEVICE | | |

Pre-Appeal Brief Request for Review

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The instant Response is filed in response to receipt of the Final Office Action mailed September 10, 2010 and the Advisory Action of December 22, 2010. A one month extension of time and a Notice of Appeal are submitted herewith.

Any required fee will be made at the time of submission via EFS-Web. In the event fees are not or cannot be paid at the time of EFS-Web submission, please charge any fees under 37 CFR § 1.16, 1.17, 1.136(a), or any additional fees to Deposit Account 13-2546.

Argument

I. Rejections under Section 103 – Claims 80 – 82, 84 – 87 and 96 - 103

In the Official Action, all remaining claims were rejected as obvious over U.S. Patent No. 5,957,861, issued to Combs, et al. in view of Scheulke, et al. (US 5,775,742). This rejection is respectfully traversed for the reasons set forth below..

A. Rejections of Claims 80 – 82, 84, 85 and 96 – 101

The Examiner's proposed combination of the references is that the measurement pulses in Scheulke should be taken during delivery of the pacing pulses.

Applicants have previously noted that the proposed combination still does not produce a device meeting the claims for three reasons, none of which are disputed by the Examiner.

1. Measurement during pacing pulses in Scheulke does not teach measurement using the same mechanism as in Combs.

Even if the measurements of impedance as in Scheulke are done during delivery of the pacing pulses, they are still done using the high voltage circuitry. Addition of the measurement system of Scheulke to Combs still produces a device with two fundamentally different impedance measuring systems, precisely as previously stated by Applicants.

Applicants' previous argument on this point was intended to address the Examiner's contention that combining the two references would produce a device in which fluid content and lead integrity are measured using the same mechanism. Neither reference suggests this conclusion.

2. Measurement during pacing pulses in Scheulke does not even teach measurement at the same time as in Combs.

The measurement of impedances as in Combs does not occur during the pacing pulses. It is done using the pacing pulse circuitry, but not during delivery of the pacing pulses. The impedance measuring drive signal applied to the tissue differs from the pacing pulses and thus cannot be done during delivery of the pacing pulses. If lead impedance measurement is done during the pacing pulses as in Scheulke as now argued by the Examiner, it cannot be incorporated into Combs and have the result of using the same mechanism to both measure lead integrity and fluid content as required by the claims. The teaching in Scheulke now relied upon by the Examiner thus teaches directly away from the claimed invention rather than making it obvious.

3. Measurement during pacing pulses as in Scheulke is irrelevant to the invention as claimed

The claims do not require measurement during the delivery of pacing pulses. The claims require that measurement occurs: (a) responsive to a cardiac event and (b) at a predetermined interval therefrom. Even if delivery of the pacing pulse is understood to be a "cardiac event", delivery during cannot be reasonably understood to be delivery at an interval therefrom. Thus, even if all impedance measurements were taken during the pacing pulses as apparently proposed by the Examiner, the claims would still not be met.

The Final Action and the Advisory Action do not address any of the above arguments or dispute any of the contentions therein.

The Advisory Action merely argues that combining the two references would be obvious, completely ignoring the Examiner's obligation to explain how the combination would produce the claimed inventions as discussed above. Clearly, significant

modifications to the cited references would be required, in addition to their simple combination.

As noted above, even if the references were combined, they are inconsistent with one another. In order to make the claimed invention obvious, the Examiner is obligated to explain how and why the references would be modified in conjunction with the proposed combination in order to produce the claimed invention. The Examiner has made no attempt to do so.

The Examiner's proposed combination is contrary to the teaching of the references and does not produce the claimed invention even if implemented as proposed by the Examiner. Under the recently issued guidelines for rejections under Section 103, the rejections are plainly deficient.

Under the circumstances, Applicants have no choice but to pursue an Appeal.

Additionally, Applicants have provided arguments for the independent patentability of many sets of the claims. These claim groups include:

- (a) Claims 86, 87, 102 and 103, related to cross-checking of measured impedances indicative of fluid content between two electrodes
- (b) Claims 81 and 97 related to declaring the set of measured impedances indicative of fluid content valid or invalid as a result of the lead integrity measurement.
- (c) Claims 87 and 103 related to declaring the set of measured impedances indicative of fluid content valid or invalid as a result of the cross-check measurement.
- (d) Claims 84, 85, 86, 99, 100 and 101 (as renumbered), related to comparing the set of measured impedances indicative of fluid content to prior measured impedances and declaring the data set valid or invalid as a result of this comparison.

Applicants have previously noted that neither of the cited references discloses these relevant claim limitations. The Examiner has never disputed this fact. The Examiner has never responded in any way to these issues and has not indicated in any way how the missing teachings would obviously result from combining the references.

The rejections of claims 81, 84, 85, 86, 87, 97, 100, 101, 102 and 103 are respectfully asserted to be legally deficient under the recently issued guidelines for rejections under Section 103. Respectfully, the time, money and resources necessary to pursue the appeal of these claims seems totally unnecessary.

Conclusion

All remaining claims are respectfully asserted to be allowable over the Combs '949 patent in view of the Scheulke patent. Reconsideration of the rejections of the remaining claims is respectfully requested.

If any new grounds of rejection are proposed for substantively un-amended claims, it is respectfully asserted that they should be properly set forth in a non-final office action as required by the rules.

Should any issues remain outstanding, the Examiner is urged to telephone the undersigned to expedite prosecution. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

Date: January 20, 2011

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